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EXAMINER	
LY, CHEYNE D	

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 10/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/087,049	FU, CHI YUNG	
	Examiner	Art Unit	
	Cheyne D Ly	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 July 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) *9 and 29* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8,10-28 and 30* is/are rejected.

7)☒ Claim(s) *3 and 21* is/are objected to.

8)☒ Claim(s) *1-30* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicants' arguments filed July 29, 2004 have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

2. The new abstract has been accepted.

3. The withdrawal of claim 9 has been acknowledged. The withdrawal of claim 29 due to being directed to the non-elected group has been maintained.

4. Claims 1-8, 10-28, and 30, living humans, staphylococcus aureus, diabetes, and acetone are examined on the merits.

5. NON-FINAL OFFICE ACTION.

OBJECTION

6. Claim 3 is objected to because of the following informalities: The phrase "claims 1" in line 1 has a typographical error. Appropriate correction is required.

7. Claim 21 is objected to because of the following informalities: The phrase "where in" in line 1 has a typographical error due to the spacing between the terms "where" and "in". Appropriate correction is required.

CLAIM REJECTIONS - 35 U.S.C. § 112, SECOND PARAGRAPH

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 2, 14, and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

10. Claims 2 and 14, lines 2-3, the phrase "other erroneous contributions" causes said claims to be vague and indefinite because it is unclear as to what criteria are being used to determine that other contributions are "erroneous." Are all contributions not "environmental" considered to be other contributions; therefore, said contributions are considered to be "erroneous"? Further, does the "correction algorithm eliminate environmental and other erroneous contributions to the markers" or the detected marker data? Clarification of the metes and bounds is required. Claim 15 is rejected for being dependent from claim 14.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

12. Claims 1-8, 10-15, 23-25, and 30 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by Pavlou et al. (2000).

13. It is noted that the instant claims have been examined as directed to the elected species even though not all of the elected species have been specifically recited in said rejected claims. Further, the elected species of acetone has been reasonably construed as colorless, volatile, extremely flammable liquid ketone, CH_3COCH_3, as defined by dictionary.com.

14. Pavlou et al. discloses a method for determining a condition directed to *Staphylococcus aureus* as defined by the set of volatile markers such as ketones (acetone) described in Table 2, as in instant claim 30.

15. The method and apparatus of Pavlou et al. comprise a 3-layer back propagation neural network, a gas sensor array of high reproducibility, and a hybrid intelligent model, expert system (Abstract etc. and page 334). The intelligent system is applicable to determining a condition of a patient (individual entity or person) (page 341, column 1, lines 1-5) to address the need for "smart breath and clinical analysers" (page 340, column 2, last paragraph), as in claims 1, 4, 6, 7, 11, 13, and 23.

16. Pavlou et al. discloses a 3-layer neural network used to discriminate between pre-described classes and a correction algorithm for eliminating noise and errors (page 336, column 2, lines 1-21). The cited disclosure above is consistent the instant disclosure in the specification for the limitation of "fuzzy filter system", as in instant claims 2, 5, 14, and 25.

17. The intelligent system (artificial) is similar to the mammalian olfactory system (Abstract etc.), as in instant claims 3, 12, and 24.

18. The method of Pavlou et al. is an improvement the well known in the art "electronic noses" for determining diabetes (page 334, column 1, last paragraph, to column 2, line 2), as in instant claim 8.

19. Table 1 (page 334) discloses markers which correlate with a single condition ("supermarkers" as defined on page 6) and collective markers to indicate the condition of infectious disease (single condition), as in instant claim 10.

20. Due to the vague and indefinite issued of claims 14 and 15 discussed above, the limitation of "the environmental correction" has been interpreted reasonably broad. Therefore, the correction algorithm for eliminating noise and errors (page 336, column 2, lines 1-21) is consistent with the broadly interpreted limitations of claim 15.

CLAIM REJECTIONS - 35 USC § 103

21. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

22. Claims 1-8, 10-17, 21-25, 27, and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pavlou et al. (2000) taken with Phillips (US 6,221,026 B1).

23. Pavlou et al. describes the invention as recited in claims 1-8, 10-15, 23-25, and 30.

24. Further, the method of Pavlou et al. is directed the ketone marker (acetone) (page 334, Table 2), as in instant claim 21.

25. However, Pavlou et al. does not describe the limitations recited in claims 16, 17, 22, and 27.

26. Phillips describes a method directed to the diagnosis of disease by employing breath testing for the detection of particular diseases in humans. The method of Phillips provides an improvement for a simpler, safer, less painful and less expensive means screening for diseases (column 1, lines 4-43).

27. Cell membrane fatty acids are degraded to alkanes by lipid peroxidation (column 7, lines 31-39), as in instant claims 16 and 17.

28. Further, Phillips discloses oxygen free radical activity increases in ischemic heart disease (column 4, lines 37-39), as in instant claims 22.

29. Phillips describes an apparatus for the detection of volatile markers (artificial olfactory system) comprising a microprocessor-controlled device and a heated breath reservoir (column 10, lines 40-67 to column 11, lines 17), as in instant claim 27.

30. An artisan of ordinary skill in the art at the time of the instant invention would have been motivated by the improvement disclosed by Phillips for a simpler, safer, less painful and less expensive means for screening diseases to improve the method of Pavlou et al. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention was made to use a simpler, safer, less painful and less expensive means for screening diseases as taught by Phillips and Pavlou et al.

31. Claims 1-8, 10-25, 27, and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pavlou et al. (2000) taken with Phillips (US 6,221,026 B1) in view of Matteucci et al. (2000), Kanety et al. (1994).

RESPONSE TO ARGUMENTS

32. Applicant's argument directed to Gardner et al. (1996), Matteucci et al. (2000), Kanety et al. (1994), and Brook et al. (1995) wherein there is no basis to combine the above references to render the claimed invention obvious of the prior art. The Gardner et al. and Brook et al. references have been withdrawn from the instant rejection; therefore, the response below is directed to Matteucci et al. (2000), Kanety et al. (1994), and the newly applied references. It

is noted that the method of Phillips is directed to the diagnosis of disease by employing breath testing for the detection of particular diseases in humans. The method of Phillips "opens non-invasive window on normal metabolic pathways, and also illustrates how these pathways are altered in disease." The non-invasive method of Phillips provides an improvement for a simpler, safer, less painful and less expensive means for screening for diseases. Further, said diagnoses have been confirmed in many different laboratories by employing progressively more sophisticated and sensitive assays (column 1, lines 4-43). Therefore, the cited description and motivation above would have motivated one of skill in the art at the time of the instant invention to improve on the clinical and diagnostic methods of Matteucci et al. (2000), Kanety et al. (1994), and Pavlou et al. for a simpler, safer, less painful and less expensive method.

33. Arguments directed to the specific limitations of the claimed invention being absent from the cited prior art have been addressed below.

34. Pavlou et al. and Phillips describe the invention as recited by claims 1-8, 10-17, 21-25, 27, and 30.

35. However, Pavlou et al. and Phillips do not describe the invention as recited by claims 18-20.

36. Matteucci et al. discloses use of biological markers as major predictors of type 1 diabetes wherein blood glucose is measured and diabetic patients wherein diabetic patients had higher level of blood glucose than control subjects (Abstract etc.). Matteucci et al. hypothesized (predict) that oxidative stress even precedes diabetes (page 1182, column 2, lines 22-24) and

enhanced levels of free radicals found in diabetes and impaired glucose tolerance have long been assumed to be related to chronically elevated glucose levels (page 1184, columns 2-3, Conclusions §), as in instant claims 18 and 19.

37. Kanety et al. discloses a method of using markers such as insulin receptors for diagnosing the effects of overeating as directed to diabetes mellitus, as in instant claim 20.

38. An artisan of ordinary skill in the art at the time of the instant invention would have been motivated by the improvement disclosed by Phillips for a simpler, safer, less painful and less expensive means for screening diseases (column 1, lines 4-43) to improve on the method of Pavlou et al., Matteucci et al., and Kanety et al. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention was made to use a simpler, safer, less painful and less expensive means for screening diseases as taught by Phillips, Pavlou et al., Matteucci et al., and Kanety et al.

39. Claims 23-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pavlou et al. (2000) taken with Phillips (US 6,221,026 B1) in view of Lewis (US006170318B1).

40. Pavlou et al. and Phillips describe the invention as recited by claims 23-25 and 27.

41. However, Pavlou et al. and Phillips do not describe the invention as recited by claims 26 and 28.

42. Lewis describes a system for detecting analyte comprising an array of sensors (column 4, lines 19-31) wherein said system is used to monitor and detecting volatile markers from an individual patient (Figure 20) for disease monitoring as directed to said (column 20, lines 7-39). The detection device of Lewis which has a neural network is employed in a microwave oven (column 17, lines 59-66), as in instant claims 26 and 28.

43. An artisan of ordinary skill in the art at the time of the instant invention would have been motivated by the improvement disclosed by Phillips for a simpler, safer, less painful and less expensive means for screening diseases (column 1, lines 4-43) to improve on the method of Pavlou et al. and Lewis. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention was made to use a simpler, safer, less painful and less expensive means for screening diseases as taught by Phillips, Pavlou et al., and Lewis.

CONCLUSION

44. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

45. Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

46. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

47. Any inquiry concerning this communication or earlier communications from the examiner should be directed to C. Dune Ly, whose telephone number is (571) 272-0716. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

48. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (571) 272-0722.

C. Dune Ly
10/15/04

Ardin H. Marschel 10/17/04
ARDIN H. MARSCHEL
PRIMARY EXAMINER